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SEP 10 2009

Bonutti Research, Inc. – Unity Ultrasonic System
K090175
June 29, 2009

510(k) SUMMARY

The following information is submitted in accordance with the requirements of 21 CFR 807.92:

Contact Person: Patrick Balsmann, MBA, MS, RAC
Director, Regulatory/Clinical Affairs & QA
Bonutti Research, Inc.,
P.O. Box 1367
Effingham, Illinois 62401
Phone: (217) 342-3412, ext. 321
Fax: (217) 342-1043

Date Prepared: June 29, 2009

Proprietary Name: Unity Ultrasonic System

Common Name: Fixation Device

Classification Name: Fastener, Fixation, Biodegradable, Soft Tissue.

Device Description: The Unity Ultrasonic System is designed for the fixation of soft tissue, ligament, tendon, and bone. Absorbable poly-L-lactic acid (PLLA) implant materials are ultrasonically welded, staked, and/or joined to secure soft tissue, ligament, tendon, and bone at a repair site. An electrical generator provides ultrasonic energy to the end effector of a handpiece to fix the implant materials together and secure soft tissue, ligament, tendon, and/or bone. The system provides a means of sutureless fixation that facilitates overall suture management. Modifications are being made to the electrical generator and ultrasonic handpiece components of the ultrasonic system to improve overall system performance and to enhance user interface features. Additionally, the handpiece is being modified to include a force sensor mechanism that allows the surgeon feedback on the amount of load they are applying to the handpiece. Feedback is provided to the surgeon through an audible tone.

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Indications for Use: The Unity Ultrasonic System consists of an electrical generator and ultrasonic handpiece. The system is to be used with existing Unity Alpha single patient use absorbable (PLLA) implants intended for use as fasteners (anchors) in the fixation of tissue, ligament, tendon, and bone. The system is indicated in general soft tissue approximation/ligation.

Predicate Device(s): The Unity Ultrasonic System is similar in design and intended use to existing Bonutti Research, Inc., electrical generators and ultrasonic handpieces used in sutureless fixation and previously determined substantially equivalent.

Predicate Comparison: Design verification testing identified and conducted as part of an overall risk analysis assessment compared the electrical output of the modified Unity Ultrasonic System electrical generator and ultrasonic handpiece to similar component predicate devices. Mechanical strength testing was also conducted with Unity Alpha PLLA implants for both the modified Unity Ultrasonic System and its predicate ultrasonic systems.

Submitted by:

Patrick Balsmann, MBA, MS, RAC
Director, Regulatory/Clinical Affairs & QA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Bonutti Research, Inc.
% Mr. Patrick G. Balsmann
2600 South Raney Street
P.O. Box 1367
Effingham, IL 62401

SEP 1 0 2009

Re: K090175
Trade/Device Name: Unity Ultrasonic System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC, MAI
Dated: August 27, 2009
Received: August 28, 2009

Dear Mr. Balsmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K090175

Device Name: Unity Alpha System

Indications For Use: The Unity Ultrasonic System consists of an electrical generator and ultrasonic handpiece. The system is to be used with existing Unity Alpha single patient use absorbable (PLLA) implants intended for use as fasteners (anchors) in the fixation of tissue, ligament, tendon, and bone. The system is indicated in general soft tissue approximation/ligation.

Prescription Use__X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090175